

laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Compliance date means the date by which a source subject to the emissions standards in § 63.362 is required to be in compliance with the standard.

Effective date means the date of promulgation in the FEDERAL REGISTER notice.

Initial startup date means the date when a source subject to the emissions standards in § 63.362 first begins operation of a sterilization process.

Manifolding emissions means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Maximum ethylene glycol concentration means any concentration of ethylene glycol in the scrubber liquor of an acid-water scrubber control device established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Maximum liquor tank level means any level of scrubber liquor in the acid-water scrubber liquor recirculation tank established during a performance test when the scrubber achieves at least 99-percent control of ethylene oxide emissions.

Oxidation temperature means the temperature at the outlet point of a catalytic oxidation unit control device or at the exhaust point from the combustion chamber for a thermal oxidation unit control device.

Parametric monitoring means monitoring of a specific operating parameter of the control device that demonstrates that the control device is operating under conditions that meet the standard.

Source(s) using less than 1 ton means source(s) using less than 907 kg (1 ton) of ethylene oxide within all consecutive 12-month periods after December 6, 1996.

Source(s) using 1 ton means source(s) using 907 kg (1 ton) or more of ethylene oxide within any consecutive 12-month period after December 6, 1996.

Source(s) using 1 to 10 tons means source(s) using 907 kg (1 ton) or more of ethylene oxide in any consecutive 12-month period but less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using less than 10 tons means source(s) using less than 9,070 kg (10 tons) of ethylene oxide in all consecutive 12-month periods after December 6, 1996.

Source(s) using 10 tons means source(s) using 9,070 kg (10 tons) or more of ethylene oxide in any consecutive 12-month period after December 6, 1996.

Sterilization chamber means any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

Sterilization chamber vent means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

Sterilization operation means any time when ethylene oxide is removed from the sterilization chamber through the sterilization chamber vent or the chamber exhaust vent or when ethylene oxide is removed from the aeration room through the aeration room vent.

§ 63.362 Standards.

(a) Each owner or operator of a source subject to the provisions of this subpart shall comply with these requirements on and after the compliance date specified in § 63.360(g). The standards of this section are summarized in Table 1 of this section.

TABLE 1 OF SECTION 63.362.—STANDARDS FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND FUMIGATORS

| Existing and new sources | Source type | Sterilization chamber vent | Aeration room vent | Chamber exhaust vent |
|--------------------------|--|---|---|--|
| Source size | <907 kg (<1 ton) | No controls required; minimal recordkeeping requirements apply (see § 63.367(c)). | No control | Maximum chamber concentration limit of 5,300 ppm prior to activation of the chamber exhaust ¹ (see § 63.362(e)(2)). |
| | ≥907 kg and <9,070 kg (≥1 ton and <10 tons). | 99% emission reduction (see § 63.362(c)). | 1 ppm maximum outlet concentration or 99% emission reduction (see § 63.362(d)). | Manifold to a control device used to comply with § 63.362 (c) or (d) or 99 percent emission reduction (see § 63.362(e)(1)). |
| | ≥9,070 kg (≥10 tons) | 99% emission reduction (see § 63.362(c)). | | |

¹ Affected sources may show compliance by manifold emissions to a control device used to comply with § 63.362 (c) or (d) by reducing emissions by at least 99 percent.

(b) *Applicability of emission limits.* The emission limitations of paragraphs (c), (d), and (e) of this section apply during sterilization operation. The emission limitations do not apply during periods of malfunction.

(c) *Sterilization chamber vent at sources using 1 ton.* Each owner or operator of a sterilization source using 1 ton shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.

(d) *Aeration room vent at sources using 10 tons.* Each owner or operator of a sterilization source using 10 tons shall reduce ethylene oxide emissions to the atmosphere from each aeration room vent to a maximum concentration of 1 ppmv or by at least 99 percent, whichever is less stringent, from each aeration room vent.

(e) (1) *Chamber exhaust vent at sources using 10 tons.* Each owner or operator of a sterilization source using 10 tons shall either reduce ethylene oxide emissions to the atmosphere by manifolded emissions from each chamber exhaust vent to a control device used to comply with paragraphs (c) or (d) of this section or shall reduce ethylene oxide emissions by at least 99 percent from each chamber exhaust vent (without manifolded).

(2) *Chamber exhaust vent at sources using 1 to 10 tons.* Each owner or operator of a sterilization source using 1 to 10 tons shall limit ethylene oxide emissions from the chamber exhaust vent to the atmosphere to a maximum concentration of 5,300 ppmv from each chamber exhaust vent. If the owner or operator chooses to limit emissions to 5,300 ppmv concentration through the use of a control device, the owner or operator may choose either to manifold ethylene oxide emissions from each chamber exhaust vent to a control device used to comply with paragraph (c) of this section or to reduce ethylene oxide emissions by at least 99 percent (without manifolded).

§ 63.363 Compliance and performance testing.

(a) (1) The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 of subpart A of this part

according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g).

(b) The following procedures shall be used to determine compliance with the emission limits under § 63.362(c), the sterilization chamber vent standard:

(1) During the performance test required in paragraph (a) of this section, the owner or operator shall determine the efficiency of control devices used to comply with § 63.362(c) using the test methods and procedures in § 63.365(b)(1). The owner or operator shall also determine the following:

(i) For facilities with acid-water scrubbers, the owner or operator shall establish as a site-specific operating parameter during the test methods and procedures in § 63.365(b)(1) either:

(A) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(B) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(ii) For facilities with catalytic oxidizers or thermal oxidizers, the owner or operator shall establish as a site-specific operating parameter the baseline temperature during the performance test in § 63.365(b)(2) using the procedures described in § 63.365(f)(1).

(2) Following the date on which the initial performance test is completed, the owner or operator shall comply with one of the following provisions:

(i) For facilities with acid-water scrubbers, operation of the facility with an ethylene glycol concentration in the scrubber liquor in excess of the maximum ethylene glycol concentration or the liquor tank level in excess of the maximum liquor tank level shall constitute a violation of the sterilization chamber vent standard.

(ii) For facilities with catalytic oxidizers or thermal oxidizers, operation of the facility with the oxidation temperature, averaged over three cycles, more than 5.6 °C (10 °F) below the baseline temperature shall constitute a